

[Trifloxystrobin]

(TXR 013599)

(8-3-99) 33
Primary Eye Irritation Study (81-4)

EPA Reviewer: Deborah C. Smegal

_____, Date ____

Toxicology Branch II (7509C)

EPA Secondary Reviewer:

_____, Date ____

Toxicology Branch II (7509C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit
OPPTS 870.2400 [§81-4]

DP BARCODE: 243979

SUBMISSION CODE: S538757

P.C. CODE: 129112

TOX. CHEM. NO.:

TEST MATERIAL (PURITY): CGA 279202 50WG-B (50.3% a.i.)

SYNONYMS: Trifloxystrobin

CITATION: Kuhn, J.O. 1997. Primary Eye Irritation Study in Rabbits. Stillmeadow, Inc. 12852 Park One Drive. Sugar Land, TX. Laboratory study number: 3815-97. Novartis Nexus Number: 596:97. December 3, 1997. MRID 44496631. Unpublished.

SPONSOR: Novartis Crop Protection, Inc.

EXECUTIVE SUMMARY: In a primary eye irritation study [MRID 44496631], 0.0563 mL (100 mg) of CGA 279202 50WG-B formulation (50.3% a.i.) as a finely ground powder was instilled into the conjunctival sac of the right eye of young adult albino New Zealand rabbits (3/sex nonwashed) for 24 hours. In addition, the treated eyes of 3 males were washed 30 seconds after treatment. Animals then were observed for 7 days. Irritation was scored by the Draize technique.

Grades 1 and 2 corneal opacity were each noted in one nonwashed treated eye 24 hours after treatment, which subsided by 72 hours post treatment. In addition, grades 2 or 3 conjunctival irritation were observed in 5 of 6 nonwashed treated eyes 24 hours post treatment, with irritation clearing by 7 days post treatment. **In this study, CGA 279202 50WG-B formulation (50.3% a.i.) is a mild eye irritant and is classified in TOXICITY CATEGORY III for primary eye irritation based on observations in both sexes.**

This study is classified as acceptable guideline and satisfies the guideline requirement for a primary eye irritation study (81-4) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. Flagging statements were not provided.

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SignOff Date:	8/3/99
DP Barcode:	D243979
HED DOC Number:	013599
Toxicology Branch:	TOX2